

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

AMGEN INC.  
and AMGEN MANUFACTURING,  
LIMITED

Plaintiffs,

v.

SANDOZ INC.,

Defendant.

Civil Action No. 1:23-cv-02406-CPO-EAP

**STIPULATED ORDER AND INJUNCTION**

WHEREAS Amgen Inc., AML and Sandoz Inc, were involved in litigation in the United States District Court for the District of New Jersey, Civil Action No. 23-02406-CPO-EAP, involving Amgen’s patents covering its denosumab antibody, pharmaceutical compositions containing denosumab, and methods of manufacture, stemming from Sandoz’s filing of BLA No. 761362 seeking FDA approval of biosimilar versions of Amgen’s Prolia® and XGEVA® (the “Sandoz Denosumab Litigation”);

WHEREAS on March 5, 2024, FDA approved Sandoz’s BLA No. 761362 for Jubbonti (denosumab-bbdz) as a 60 mg/mL solution in a single dose prefilled syringe assembled with a needle safety device and Wyost (denosumab-bbdz) as a 120 mg/1.7 mL solution in a single dose vial, both as described in greater detail therein, FDA authorized Sandoz to introduce or deliver into U.S. interstate commerce, Sandoz Biosimilar Products under Sandoz’s existing Department of Health and Human Services U.S. License No. 2003;

WHEREAS Amgen Inc., AML and Sandoz Inc. settled the Sandoz Denosumab Litigation, executing a Confidential Binding Settlement Term Sheet on April 29, 2024 (“the Binding Term Sheet”), and will prepare a long form settlement agreement, as provided therein, which shall not alter the terms stated in the Binding Term Sheet;

WHEREAS, as a part of the Binding Term Sheet, the Parties agreed that the Sandoz Biosimilar Products infringe the Boyle ’736 Patent and that the Boyle ’736 Patent is valid and enforceable as to the Sandoz Biosimilar Products;

WHEREAS, as a part of the Binding Term Sheet, the Parties agreed that infringement of the Boyle ’736 Patent will result in an irreparable harm to Amgen and that Amgen need not make a further showing on balance of the harms or public interest;

WHEREAS, as a part of the Binding Term Sheet, the Parties agreed that the Court would enter an injunction that enjoined and prohibited Sandoz and third parties acting on behalf of or in active concert with Sandoz from making, using, selling, offering to sell or importing the Sandoz Biosimilar Products into the Territory until the expiration of the Boyle Patent (February 19, 2025), except as provided for in the Binding Term Sheet and except as described in 35 U.S.C. § 271(e)(1);

WHEREAS the parties agreed that Sandoz can conduct any and all activities that are protected under 35 U.S.C. § 271(e)(1) or that are not an act of infringement under 35 U.S.C. § 271;

WHEREAS the definitions and terms of the Binding Term Sheet shall apply to any disputes between the parties regarding the enforcement of this order but are not restated here for reasons of convenience and confidentiality;

WHEREAS the parties have waived the entry of findings of fact and conclusions of law under Rule 65 of the Federal Rules of Civil Procedure.

THEREFORE based on the parties' stipulation and consent as reflected in the Binding Term Sheet, it is ORDERED, ADJUDGED, and DECREED as follows:

1. The Court has jurisdiction over the subject matter of the above-captioned case pursuant to 28 U.S.C. § 1331 and 1338(a).

2. The Court has personal jurisdiction over the parties, and venue is proper as to all parties pursuant to 28 U.S.C. § 1391(b), (c), and 1400(b).

3. The Court retains jurisdiction to enforce or supervise performance under this Order and Injunction and the parties' Binding Term Sheet dated April 29, 2024 and subsequent long form settlement agreement.

4. The asserted claims of U.S. Patent No. 7,364,736 (the "Boyle '736 Patent") are valid, enforceable and infringed by making, using, selling, or offering to sell Jubbonti and Wyost in the United States, its territories, districts, commonwealths and possessions, including without limitation Commonwealth of Puerto Rico and the District of Columbia ("Territory"), or by the import of Jubbonti and Wyost into the Territory.

5. Subject to and pursuant to the terms of the Binding Term Sheet, Sandoz, including its Affiliates, its officers, agents and employees, and third parties acting on behalf of or in active concert with Sandoz is hereby enjoined from making, using, offering to sell, or selling Jubbonti or Wyost in the Territory, or importing Jubbonti or Wyost into the Territory, except as permitted under the Binding Term Sheet, or by 35 U.S.C. § 271(e)(1). Capitalized Terms shall have the meaning ascribed to them in the Binding Term Sheet. The foregoing injunction expires on February 19, 2025.

6. Subject to the terms of the Binding Term Sheet, the parties' remaining claims and counterclaims in the above-captioned matter are dismissed with prejudice.


7. The injunction, determinations, admissions and dismissals with prejudice stated above are made solely for purposes of the Sandoz Biosimilar Products and for purposes of the Sandoz Denosumab Litigation only, as those terms are used in the Binding Term Sheet. They shall not have any preclusive or other effect on a Different Product Claim or Non-Territory Claim, as those terms are used in the Binding Term Sheet.

8. Judgment is entered with respect to the Boyle '736 Patent, and this order fully resolves the remaining claims and counterclaims.

9. Except as expressly provided in the Binding Term Sheet, each party shall bear its own costs.

**IT IS SO ORDERED.**

Dated: 4/29/24

  
Hon. Christine P. O'Hearn  
United States District Judge